



**Institutional Review Board**

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**CONSENT TO PARTICIPATE**

<b>Project Title</b>	Contagious Phenotypes of Acute Respiratory Infection: Identification, Characterization, and Biomarkers {Characterizing And Tracking College-community Health (CATCH) – the Virus Study}
<b>Purpose of the study</b>	This research is being conducted by Donald Milton, MD, DrPH and a team of researchers at the University of Maryland (UMD) with funding from the U.S. Defense Advanced Research Projects Agency (DARPA) and the Biomedical Advanced Research and Development Authority (BARDA). We are inviting you to participate in this research project because you live, work, or attend classes on the UMD campus, or you are a household contact of such a person including students at the Children and Youth Center, or you live near the College Park campus and are willing to come to the School of Public Health (SPH) for research clinic visits. The purpose of this research project is to identify chemical biomarkers (measurable substances within a person) and physiologic biomarkers (such as heart rate, movement, breathing, or sweating measured by a wearable device) that can indicate which individuals, when exposed to viruses and bacteria that cause Acute Respiratory Infections (ARI), are likely to become contagious and spread the ARI to others, and to improve our understanding of how ARI are transmitted so that we may better prepare to mitigate or prevent future epidemics and pandemics of influenza and other ARIs.
<b>Procedures:</b>	If you are age 18 or older and you have a smartphone that is compatible with our wearable app, you are eligible to participate. This consent form outlines the various aspects of the study and covers the questionnaires and communications procedures including contacting you about visits described below. Collection of biological specimens, smartphone apps, and wearable device parts of the study will be described in greater detail in separate consent forms.  <i>Please Note: when you agree to participate in the study (by signing this consent form), you agree to participate in all procedures described below except procedures depending on</i>

*funding. You will be asked to read and sign a separate consent form for visits including biological sampling before we collect samples from you. However, you have a right to withdraw from the study at any time.*

❖ **Start- and End-of-Study Questionnaires**

**1. Baseline Questionnaire (study entry)**

Immediately after you agree to participate in the study (by signing this form), you will be asked to complete an online survey. We will ask you to provide your name, email address, phone number, social media information, and your preferred method of contact, so that we can contact you during the study. We will ask you to provide basic information about yourself such as your date of birth, sex, race and ethnicity. We will ask you some questions about your medical history, influenza vaccinations, respiratory symptoms and medications, stress, and your habits regarding sleep, exercise, smoking, and alcohol use. We will ask you to provide your dorm room number or local address, the number of persons who share your living space, and time spent in your room or residence and certain locations on campus, to assess your exposure to exhaled breath from other building occupants in these locations. We estimate it will take you approximately 10-15 minutes to enter your data and answer the questions in the database.

**2. Second Baseline Questionnaire (study completion)**

All study participants who provide blood samples will be asked to complete a second questionnaire near the end of the spring semester. You will be emailed a link and will be asked to complete a follow-up survey to update some of the information you provided when entering the study, including time spent in your room or residence, recent respiratory symptoms and illness, recent stress, and your sleep, exercise, smoking, and alcohol habits. We will also ask you about your experience using the wearable device if you have at least one provided by the study. We estimate you should be able to complete this survey in approximately 10-15 minutes.

❖ **Baseline Sample Collection & Wearable Device**

You will then be asked to come to the SPH research clinic to provide biological samples and to enroll in the wearable portion of the study.

**1. Baseline Sample Collection at Study Entry**

Trained study personnel will measure your height and weight and collect nail samples, two nasal swabs, and a blood sample from a vein in your arm. At the beginning of this visit you will be asked to read and sign a separate sample-collection consent form. Reviewing and signing the consent will take about 10-15 minutes, and sample collection will take about 20-30 minutes.

2. **Wearable Health-Monitoring Device**

You will also need to download and install an app and to pair a wearable device with your phone. Several different devices may be used, and the device and app will track multiple parameters including your heart rate, breathing, and movement. Which device you will receive will depend on the type of phone you have and whether you have an allergy to jewelry (for example, a nickel allergy). You will be asked to read and sign a separate wearable-device consent form which fully explains this part of the study, and we will provide detailed instructions for set up and use of the device and the associated app. Reviewing and signing the consent will take approximately 10 minutes when you pick up your device, and setup for the wearable will take a similar time commitment as setting up a new fitness tracker or smartwatch. You will be asked to use the app and wear the device consistently for as many hours as possible every day throughout the academic year, including while you are sleeping.

❖ **Daily Text Message and Study Communication**

Once you enroll in the wearable portion of the study, we will send you a daily text message throughout the academic year asking whether you have cold or flu symptoms - you can answer with a simple yes or no. If you answer yes, we will ask you what symptoms, when they started, and have you seen a healthcare provider. Answering the daily text takes between 10 and 30 seconds per day.

Please tell us about new cold or flu symptoms as soon as possible. You don't need to wait for the daily text to tell us about it. You can tell us right away by email, text message, phone call, or coming by the SPH research clinic. If you reply quickly and meet the study criteria, we will ask you to provide swab of your nose to test for influenza and other respiratory pathogens (e.g. adenovirus).

We want to know if and when you get a flu shot and will ask you about it on a regular basis by either including a periodic question in our daily text messages or by sending the question via email. When you get a flu shot, please save the receipt showing what brand you got and bring it in or send us a screenshot. We will also send you occasional emails with study updates and reminders about other opportunities to participate in the study.

The study website is a source for general information, copies of the consent forms, and study updates such as the number of enrolled participants and the number and types of infectious agents detected within the study group. Any information posted on the website will be anonymous, with no personally identifiable information about you.

❖ **Case Screening Visit**

Each time you tell us about cold or flu symptoms that meet our criteria we will ask you to come to the SPH research clinic for screening. We will ask you to complete a brief electronic questionnaire about contacts you may have exposed, symptoms and medications. Trained study personnel will measure your oral temperature and will collect two swabs of your nose to test for influenza and other respiratory pathogens in your nose and lungs. The screening will only take about 15-20 minutes.

If screening test results indicate you are infected with influenza, adenovirus, or one of the other respiratory infectious agents we are studying, we will ask you to return for a follow-up visit the next day to answer a questionnaire about your symptoms and medications, recent health habits, contacts, and time spent in your residence over the past 24 hours and to provide 2 nasal swabs for testing to confirm your infection. This case follow-up visit should only take about 15-20 minutes.

❖ **Contact Surveillance**

Each time you are potentially exposed to influenza or another acute respiratory infection because you have had close contact with a study participant with ARI or you live in close proximity to such a person in one of our targeted residence halls, we will notify you (via email, text message, phone call, and/or social media). We will ask you to come to the SPH research clinic as soon as possible so that we can screen you for infection. The sooner you

come the more likely we will be able to detect early infection, if you become infected. You will be asked to come to the clinic for a series of up to 5 daily surveillance visits to screen you for infection, with eligibility for more visits the sooner you start. You will be asked to answer a questionnaire about your close contacts, symptoms, medications, activities. At the first visit in the series we also ask about exercise, sleep, and stress. Trained study personnel will collect nasal swabs and blood samples for testing. We will ask you to take home a small portable indoor air monitor for several days to help us understand your environmental exposures. At your first contact surveillance visit, you will be asked to read and sign a separate consent form, which explains in detail what you would be asked to do and the time involvement in the contact surveillance. The first visit will take 45 to 60 minutes, the 2nd, 3rd, and 4th visits will take 20 to 30 minutes and the last visit will take about 15 minutes.

If our laboratory test of your nasal swabs detects an infection, we will inform you, and if it is caused by a virus that we are studying such as influenza or adenovirus, we will ask you to return and complete one more contact visit of your series to confirm your infection, but we may cancel any remaining visits thereafter. If funding is approved, we may ask you to participate in a special type of visit to investigate your case (see case investigation visit below) instead of the contact visit.

❖ **Contact Tracing and Smartphone Location Tracking App**

When you are screened or tested for ARI as a case or a contact we will ask you to sign a separate consent form and download and activate an app on your smartphone that tracks your location so that we can better trace infection transmission between contacts using the app. This app, together with indoor air quality monitors, and class schedules, will help us to identify contacts, better understand how influenza, adenovirus, and other respiratory pathogens are transmitted, and the effect of the indoor environment on infection transmission. Setting up the app requires downloading from our website (NOT the app store); it can be done in approximately 5-10 minutes.

❖ **Baseline Sample Collection at Study Completion**

If you provide blood samples during the study, you will be invited to come to the SPH research clinic at the end of the spring semester, where trained study personnel will measure and record

	<p>your height and weight and collect nail samples, two nasal swabs, and blood samples. The study completion sample collection visit will take about 20-30 minutes.</p> <ul style="list-style-type: none"> <li>❖ <b>Case Investigation (depending on funding)</b> If funding is approved, when screening shows that you have an acute respiratory infection that meets our research criteria we may invite you to participate in an investigation of your case. You would be asked to read and sign a separate consent form, answer additional questionnaires and provide additional nasal swabs, blood and exhaled breath samples for testing. You would also be asked to take home a small portable indoor air monitor to help us understand your environmental exposures and to come back for a short visit approximately 1 week later to provide additional nasal swabs and return the monitor.</li> <li>❖ <b>Data and Sample Analysis</b> Swab (and breath samples, if funded) will be analyzed for the presence of microbial agents including infectious viruses and bacteria. Blood (and breath samples, if funded) will be analyzed to identify biomarkers of acute respiratory infections. Data collected from questionnaires, wearable sensors, indoor air sensors, and location tracking will be combined with laboratory analyses of the microbes detected in swabs and breath to identify chains of infection transmission.</li> </ul>
<p><b>Potential risks and discomforts</b></p>	<p>Your participation in this study may take time away from other activities or time you may have spent resting and recuperating, if you develop an ARI and participate in screening; we will try to keep each visit as short as possible and to minimize wait times through efficient scheduling of appointments. You may not feel well while participating in the case testing part of the study due to symptoms of your illness, but participation should not exacerbate your symptoms any more than a visit to a health care provider. You may feel some embarrassment when providing information about your medical history or habits, but this will be minimized by answering the questions in a private setting on a computer or tablet. There is a small risk to your privacy and confidentiality, as we will be collecting a variety of personal data from you; we will do our best to keep your personal information confidential and limit access to only essential study personnel. All data will be transmitted between the tablet or computer used to enter the data and the server via encrypted connections and the server will be housed in a high security data center as described below under confidentiality.</p>

	<p>When you provide baseline samples or participate in ARI case or contact testing, there are very small risks associated with the collection of your nail, nasal swabs, and blood samples. These specific risks are detailed in a separate consent form and they will be discussed with you prior to your participation in these aspects of the study and before any samples are collected.</p>
<p><b>Potential benefits</b></p>	<p>There are no direct benefits of participating in the start- and end-of-study assessments, wearable sensor, and location tracking parts of this research project. However, participating may increase the likelihood that you will get screened for acute respiratory infections. Possible benefits of that screening would occur if we detected that you were infected with a pathogen that can and should be treated or for which early treatment may be advantageous. Please note that most of the pathogens that cause ARI do not require specific treatment (such as the viruses that cause the common cold). We hope that, in the future, other people might benefit from this study through improved understanding of how acute respiratory infections spread and identification of biomarkers that can predict contagiousness, in order to limit the spread of respiratory infections like influenza.</p>
<p><b>Confidentiality</b></p>	<p>Any potential loss of confidentiality will be minimized by storing all data in an encrypted database maintained on a secure server housed in a high security data center. Only essential study personnel will have access to this data. Access to data elements will also be controlled so that only study personnel with an operational need for particular information will have access to sensitive information (for example social security numbers), and undergraduate research assistants will only have access to the clinical research database during times they are actively working on the study under senior staff supervision. If you decide to participate in the study, you will be assigned a subject ID number which will be used to access your records in the database.</p> <p>Please note that your name and email address may briefly appear in a list of potential study participants that is seen by other case and/or contact participants when they are attempting to search for and name their closest contacts on study questionnaires; the presence of your name on this list does NOT confirm to others that you are an enrolled participant but is indicative that you have been targeted for possible study participation.</p> <p>All biologic samples will be labeled with a unique sample ID that can only be linked to your subject ID number by Dr. Milton and his designated</p>

	<p>research study personnel. Collaborators within and outside the University of Maryland may conduct analyses on samples or data for research purposes, but all such samples or data will always be de-identified. If we write a report or article about this research project or post information on the study website, your identity will be protected to the maximum extent possible. Your information may be shared with representatives of the University of Maryland, College Park or governmental authorities if you or someone else is in danger or if we are required to do so by law.</p> <p>The Code of Maryland Regulations (COMAR) 10.06.01.03 C, requires reporting to the Maryland Department of Health and Mental Hygiene of certain illness including personally identifiable information in the event of “any grouping or clustering of patients having similar disease, symptoms, or syndromes that may indicate the presence of a disease outbreak,” that poses a danger to public health. It also requires reporting of cases of Measles, Mumps, Pertussis and Legionellosis, which will be tested for in samples that we collect. Measles is a highly contagious virus that causes respiratory infection and rash, and Mumps is a somewhat less contagious viral illness that typically causes swollen tender salivary glands. Pertussis, also known as whooping cough, is a highly contagious bacterial respiratory infection, and Legionellosis is a bacterial infection that can cause pneumonia or flu-like illness. Measles, Mumps, and Pertussis can all be prevented through proper vaccination.</p> <p>To help us protect your privacy, we have a Certificate of Confidentiality from the U.S. Department of Health and Human Services, National Institutes of Health. This Certificate will allow us to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example if there is a court subpoena. We will use the Certificate to resist any demands for information that would identify you and any of the data we collect about you except as explained below.</p> <p>Any unanticipated problems involving risks to participants or others such as unexpected or serious adverse events, non-compliance, audits, and investigation reports will be promptly reported to the University of Maryland Institutional Review Board, as well as both the U.S. Department of the Navy and Space and Naval Warfare Systems Center Pacific Human Research Protection Programs.</p>
<b>Medical treatment</b>	<p>The University of Maryland does not provide any medical, hospitalization or other insurance for participants in this research study, nor will the University of Maryland provide any medical treatment or compensation for</p>



	<p>any injury sustained as a result of participation in this research study, except as required by law.</p>
<p><b>Compensation</b></p>	<p>You have the potential to earn up to <b>\$100</b> when you fully enroll in the study (see details below). You will receive:</p> <ul style="list-style-type: none"> <li>• <b>\$10</b> after you join the study and complete the baseline survey. (If you are not affiliated with the University and you do not have a Terrapin Express account, you must come to the School of Public Health to obtain your compensation on a University issued debit card--see below.)</li> <li>• Up to <b>\$50</b> for providing your baseline samples.</li> <li>• <b>\$20</b> to thank you for your commitment to regularly wear the wearable device. Then, you can earn up to \$35/month for wearing the device when you meet the threshold numbers of hours/day of data uploads. (See wearable consent for details; earnings will be paid biweekly.)</li> <li>• <b>\$20</b> to thank you for your commitment to respond to the daily text messages (if you have a wearable device). Then, each subsequent day that you promptly reply within 2 hours to the daily text message you will earn <b>\$1 per day or \$5 on a random day</b> each month, which equals \$35 per month (also paid biweekly) if you respond everyday.</li> </ul> <p>When you participate in additional aspects of the study as described in the procedures section above, you will receive added compensation (see the chart below for details).</p> <p><b><u>Please note:</u></b>  Because you have the potential to earn more than \$100 as a research participant in this study, you must provide your name, address, and SSN to receive compensation for study visits and for rewards for text messaging and use of the wearable device. You will be asked to provide this information at your first study visit. If you decline to provide this information you can still participate in the study, but you will not be able to receive compensation. You will be responsible for any taxes assessed on the compensation you receive during this study. You may choose to receive compensation payments for study visits and any bonuses that you earn through your participation via one of two payment vehicles: a)</p>

Terrapin Express, or b) a University issued debit card onto which funds will be electronically transferred. We will not make any cash payments.

**Summary of study visits, procedures, and compensation**

Visit/Survey	Procedures	Compensation
<b>Start-of-study questionnaire</b>	Online Survey	\$10
<b>Baseline Sample Collection at Study Entry</b>	<ul style="list-style-type: none"> <li>· Oral temperature</li> <li>· Height &amp; Weight</li> <li>· Nail samples</li> <li>· Nasal swabs</li> <li>· Venous Blood sample</li> </ul>	<p>\$50</p> <p>(includes \$10 on time bonus)</p>
<b>Wearable Device</b>	Continued use of device	<p>\$20 initial payment, then \$1/day throughout the study year with one random day of \$5 each month</p> <p>(up to \$35/month/device)</p>
<b>Reply to Daily Text Message</b>	Online Survey (very brief)	<p>\$20 for signing up, then \$1 for each subsequent day and one random day of \$5 each month (up to \$35/month)</p>
<b>Case Screening Visit</b>	<ul style="list-style-type: none"> <li>· Questionnaires</li> <li>· Oral temperature</li> <li>· Height &amp; Weight (if 1st visit)</li> <li>· Nasal swabs</li> </ul>	<p>\$25</p> <p>(includes \$10 on time bonus)</p>
<b>Case Follow-up Visit</b>	<ul style="list-style-type: none"> <li>· Questionnaires</li> <li>· Oral temperature</li> <li>· Nasal swabs</li> </ul>	<p>\$25</p> <p>(includes \$10 on time bonus)</p>
<b>Contact Surveillance First Visit in a Series</b>	<ul style="list-style-type: none"> <li>· Questionnaires</li> <li>· Oral temperature</li> <li>· Height &amp; Weight (if 1st visit)</li> <li>· Nasal swabs</li> <li>· Venous Blood sample</li> </ul>	<p>\$50</p> <p>(includes \$10 on time bonus)</p> <p>Only 50% of the compensation will be paid if you do NOT complete the next visit.</p>
<b>Contact Surveillance Second and Later Visits and Last Visit in a Series</b>	<ul style="list-style-type: none"> <li>· Questionnaires</li> <li>· Oral temperature</li> <li>· Nasal swabs</li> <li>· Venous Blood sample (unless day 5 or last day----i.e. NO blood collected at last contact visit)</li> </ul>	<p>Day 2: \$60*</p> <p>Day 3: \$70*</p> <p><u>Day 4: \$80*</u></p> <p>Day 5 or last day: \$40</p> <p>*Only 50% of the compensation will be paid if you do NOT complete the next visit.</p>
<b>End-of-study questionnaire</b>	Online Survey	\$10

	<table border="1"> <tr> <td data-bbox="456 199 688 352"> <b>Baseline Sample Collection at Study Completion Visit</b> </td> <td data-bbox="688 199 1073 352"> <ul style="list-style-type: none"> <li>· Oral temperature</li> <li>· Height &amp; Weight</li> <li>· Nail sample</li> <li>· Nasal swabs</li> <li>· Venous Blood sample</li> </ul> </td> <td data-bbox="1073 199 1408 352"> <p style="text-align: center;">\$50 (includes \$10 on time bonus)</p> </td> </tr> <tr> <td data-bbox="456 352 688 512"> <b>Contact Tracing and Smartphone Location Tracking App</b> </td> <td data-bbox="688 352 1073 512">           Continued use of app over 5 days, when eligible         </td> <td data-bbox="1073 352 1408 512"> <p style="text-align: center;">\$2 day prorated based on hours of usage over the 5 days after screening or initial contact visit for a maximum total compensation of \$10</p> </td> </tr> </table>	<b>Baseline Sample Collection at Study Completion Visit</b>	<ul style="list-style-type: none"> <li>· Oral temperature</li> <li>· Height &amp; Weight</li> <li>· Nail sample</li> <li>· Nasal swabs</li> <li>· Venous Blood sample</li> </ul>	<p style="text-align: center;">\$50 (includes \$10 on time bonus)</p>	<b>Contact Tracing and Smartphone Location Tracking App</b>	Continued use of app over 5 days, when eligible	<p style="text-align: center;">\$2 day prorated based on hours of usage over the 5 days after screening or initial contact visit for a maximum total compensation of \$10</p>
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<b>Right to withdraw and questions</b>	<p>Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify. Your academic standing as a student or employability at UMD will not be affected by your participation or non-participation in this study. Special notice for research assistants: If you are a student working on the study and are earning course credit for your work, your grade will not be affected by your decision to participate (or not participate) as part of the study cohort. If you decide to stop taking part in the study, if you have questions, concerns, or complaints, or if you need to report an injury related to the research, please contact the investigator:</p> <p style="text-align: center;"> <b>Dr. Donald Milton</b>  <b>Room 2234V SPH Building 255</b>  <b>University of Maryland College Park, MD 20742</b>  <b>Telephone: 301-405-0389</b>  <b>Email: dmilton@umd.edu</b> </p>						
<b>Participant rights</b>	<p>If you have questions about your rights as a research participant or wish to report a research-related injury, please contact:</p> <p style="text-align: center;"> <b>University of Maryland College Park</b>  <b>Institutional Review Board Office</b>  <b>1204 Marie Mount Hall</b>  <b>College Park, Maryland, 20742</b>  <b>E-mail: irb@umd.edu</b>  <b>Telephone: 301-405-0678</b> </p> <p>This research has been reviewed according to the University of Maryland, College Park IRB procedures for research involving human subjects.</p>						
	<p style="text-align: center;"><b><i>[Consent Form Quiz, see attachment 1 below, will be inserted here in the electronic version of this consent document.]</i></b></p>						

<p><b>Statement of consent</b></p>	<p>Your signature indicates that you are at least 18 years of age; you have read this consent form or have had it read to you; your questions have been answered to your satisfaction and you voluntarily agree to participate in this research study. You will be sent a copy of this signed consent form via email, which you may print.</p> <p><b>Class schedules</b>          In order to identify potential transmission in the classroom, we would like to ask, if you are a University of Maryland student, for your permission to obtain your class schedules for the current academic year from the registrar. Please place your initials on the appropriate line below.          _____YES                      _____NO                      _____Not Applicable</p> <p><b>Possible future study opportunities</b>          There may be an opportunity for you to enroll in future studies, and we would like to be able to notify you if such an opportunity develops. Please place your initials on the appropriate line below to indicate whether we have your permission to contact you for future studies.          _____YES                      _____NO</p> <p>If you agree to participate, please type your name and sign below.</p>	
<p><b>Signature and Date</b></p>	<p><b>NAME OF PARTICIPANT</b>          [Please Print]</p>	
	<p><b>DATE</b></p>	

**Consent form quiz**

[Note to IRB: if a respondent answers any of the questions incorrectly, they will be prompted to try again until selecting the correct answer before allowing the participant to type their name in the signature block]

1. My participation in this research study is voluntary, and I can withdraw at any time.

True     False

2. I will be asked to provide biological samples at study entry, after reading and signing a separate sample-collection consent form.

True  False

3. I will be asked to regularly wear and test a wearable device during this study, after reading and signing a separate wearable consent form.

True  False

4. If I start having new cold symptoms, it doesn't matter how long I take to get around to contacting the study to give samples.

True  False

5. My identity as a participant will be kept confidential except as required by law.

True  False